

DATE: June 29, 1977

SUBJECT: Glyphosate in coffee, tolerance at 1 ppm requested (PP No. 6E1809, 3/3/77 amendment) and in palm oil, tolerance at 0.1 ppm requested (FAP No. 6H5144, amendment of 3/4/77, TB response to CB (6/8/77) memos on.

FROM: TR/RD

TO: PM No. 25, Mr. R. Taylor

PP No. 6E1809
FAP No. 6H5144

Monsanto
St. Louis, Mo. 63166

CONCLUSIONS:

1) The deficiency (lack of details of liver histopath. findings in low-dose rats from 2-yr feeding study), previously noted by TB with respect to these two petitions, has been alleviated. (There remains the problem of nitrosamines.)

2) TB is presently unable to evaluate toxicologic significance of N-nitrosoglyphosate (NNG), for which CB has made estimates of amounts likely to be present in treated commodities or foods.

3) Petitioner is requested to supply any available TOX data on NNG, especially mutagenicity data.

4) Should any mutagenicity testing be carried out on NNG by Petitioner, its value would be greatly enhanced if parallel tests were carried out on the known carcinogen, N-nitrosodimethylamine.

RECOMMENDATION:

We recommend against granting requested tolerances (memo title, above) until TOX evaluation of N-nitrosoglyphosate (NNG), which CB now estimates to be present in limited amount in these commodities (palm oil and coffee), can be carried out. (Conclusions 3 and 4 (above) should be communicated to Petitioner.)

INTRODUCTION:

CB (memos of 6/8/77 by Mr. D. Duffy, these petitions) finds that there is 0.2 to 0.4 ppm N-nitrosoglyphosate (NNG) in formulated glyphosate, "Roundup." If all NNG therein were transferred to treated crops, they would contain 10 to 20 ppb NNG. Due to photosensitivity of NNG to UV light, actual residues in food items would be expected to be less than that. Treated crops showed "no detectable levels" of NNG (less than 0.02 ppm) by direct analysis. C¹⁴-glyphosate metabolism data for 22 crops yield hypothetical maximum residues of NNG of less than 1 to 7 ppb in them.

June 29, 1977

CB defers to TB as to significance of these levels of NNG in food items. CB "can make no estimate of possible hazard to pesticide applicators using the product in the field."

TOXICOLOGIC ASPECTS:

No new toxicology data accompany the amendments. TB's latest memos on these petitions (by Mr. R. Landolt, 3/15/77) recommend withholding approval of requested tolerances pending submission of details of liver histopathologic changes in 30- and 100-ppm rats (2-yr glyphosate study, PP No. 5F1536). However, this has been taken care of satisfactorily (cf. TB memo of 4/18/77 by Dr. M. Quaife in PP No. 6F1758/FAP No. 6H5126).

There remains, therefore, TB evaluation of possible hazard caused by N-nitrosoglyphosate (NNG) in oil of treated palms and in coffee.

However, we have no TOX data on NNG, on which to evaluate its toxicity. Nor do we know of any firmly established "no-effect" levels for nitrosamines in general or in particular, with respect to carcinogenicity.

Therefore, we request Petitioner to forward any and all toxicity data he can gather with regard to N-nitrosoglyphosate. Especially we request data on its mutagenic potential. Such tests, if carried out, would be greatly enhanced for our present purpose, if parallel tests on N-nitrosodimethylamine, a known carcinogen, were also carried out.

Mary L. Quaife, Ph.D., TB/RD
June 29, 1977